

REMARKS

Claims 1-18 are pending. Claims 2-5, 7, 8, 13 and 15-18 are withdrawn from examination. Claims 1, 6, 9-12 and 14 are presently under examination.

Rejection under 35 U.S.C. §112, First Paragraph:

Claims 1, 6-9, 12 and 14 are rejected under 35 U.S.C. §112, first paragraph for lack of adequate written description. The Office Action states that “the claims lack support for the negative limitation ‘where the COX-2 inhibitor is not nimesulide.’” The Office Action states “No support for this negative limitation is found in the original specification.” Applicants respectfully disagree.

Explicit support for the negative limitation is found, for example, in the Abstract, at page 25, which states “The method comprises administering to the patient in need thereof a therapeutically effective amount of at least one COX-2 inhibitor, wherein the COX-2 inhibitor is not nimesulide.” Further support is found, for example, in the first paragraph of the Summary of the Invention (paragraph [0010] on page 4, lines 5-7), which recites “The method comprises administering to the patient in need thereof a therapeutically effective amount of at least one COX-2 inhibitor, wherein the COX-2 inhibitor is not nimesulide.” Further support is found in the first paragraph of the Detailed Description of the Invention, at paragraph [0022], which recites “The method comprises administering to the patient in need thereof a therapeutically effective amount of at least one COX-2 inhibitor, wherein the COX-2 inhibitor is not nimesulide.”

Finally, Applicant notes that the Office Action makes reference to a lack of support “in the original specification.” The direct support noted above occurs in the original utility application, i.e., the instant application. However, lest there be any doubt, the limitation occurs in the U.S. provisional application, Serial No. 60/443,453, filed January 29, 2003, from which the instant application claims priority. See, for example, paragraph [007], on page 3 of that provisional application, which states:

“The present invention provides a method for the minimization or prevention of adhesion formation during or following a surgical procedure. The method

comprises administering to the patient in need thereof a therapeutically effective amount of at least one COX-2 inhibitor, wherein the COX-2 inhibitor is not nimesulide.”

In view of this explicit and direct support, applicants submit that there is adequate support for the negative limitation. Reconsideration and withdrawal of the rejection is respectfully requested.

Claim Objection:

Claim 6 is objected to under 37 C.F.R. §1.75(c) as failing to further limit the subject matter of the previous claim. The Office Action states:

“Claim 6 sets out that the surgical adhesion is between an organ or tissue. All adhesions are between some organ or some tissue, so the claim fails to set out any limitation which further narrows the treatment to any specific tissue.”

Applicants respectfully disagree.

Claim 6 limits the adhesions to being “between organ or tissue *surfaces*” and thereby further limits the scope of claim 1. Nonetheless, in the interest of advancing prosecution, Applicants have cancelled claim 6 herein without prejudice. Claim 1 encompasses surgical adhesions between tissue and/or organ surfaces.

Rejections under 35 U.S.C. §103:

Claims 1, 6, 9-12 and 14 are rejected 35 U.S.C. §103(a) as obvious over WO 00/32189 in view of Saed et al. The Office Action states:

WO’189 teaches that COX-2 inhibitors in general, and more specifically celecoxib are useful in treating post-operative inflammation (see page 9, line 2-3). As well as any cox-2 mediated condition or disorder. Surgical adhesions however, are not specifically recited for treatment.

However, Saed et al suggest the link between surgical adhesions and cox-2 expression in intraperitoneal adhesions (see main outcome measures, page 1404). Saed et al further teach that both preoperative and postoperative adhesions were reduced by administration of nimulside (see page 1408, second paragraph). The article goes on to suggest that Cox-2 inhibitors in general may be used to regulate surgical adhesions (see page 1408, last paragraph). The teaching of WO’189 associated COX-2 inhibitors with any COX-2 mediated condition, and Saed et al identifies surgical adhesions as a condition associated with COX-2 inhibitors.

The Ordinary practitioner would have therefore found it well within his or her skill to claim the instant therapeutic regimen given the teachings of Wo'189 in view of Saed et al, with a reasonable expectation of inhibiting surgical adhesions. There are no unusual and/or unexpected results which would rebut prima facie obviousness. As such, the instant method of inhibiting surgical adhesions through administration of COX-2 inhibitors would have been obvious to one of ordinary skill at the time of invention given the teachings of WO'189 in view of Saed et al.

Applicants respectfully disagree.

Applicants submit that Saed et al., Fertil. Steril. 79(6), 1404-1408, published in June, 2003, is not prior art. The present application claims priority to U.S. provisional application No. 60/443,345, filed January 29, 2003, before the publication of the Saed et al. reference. The '345 priority application described inhibition of adhesion formation during or following a surgical procedure by administering to the patient in need thereof a therapeutically effective amount of at least one COX-2 inhibitor. As noted above, the '345 priority document also recited the negative limitation that the COX-2 inhibitor is not nimesulide. See, e.g., the whole priority document, but particularly paragraph [007].

Because the Office Action acknowledges that WO 00/321189 does not teach treatment of surgical adhesions, and because Saed et al. is not properly prior art, the combination fails to support the obviousness rejection under §103(a). Reconsideration and withdrawal of the rejection is respectfully requested.

In view of the above, all issues raised in the Office Action have been addressed herein. Reconsideration of the claims is respectfully requested.

In the event that there are any questions relating to this response, it is kindly requested that the Examiner contact the undersigned attorney concerning the same.

Fee deficiencies may be charged and overpayments credited to the NIXON PEABODY
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Respectfully submitted,

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